
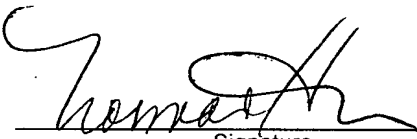


PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) NY-LUD 5466.7 DIV	
	Application Number 10/023,182	Filed December 17, 2001	
	First Named Inventor Elisabeth Stockert et al.		
	Art Unit 1642	Examiner M. T. B. Davis	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal, together with a one-month extension request and fee therefore.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>30,946</u></p> <p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. <u>30,946</u></p> <p> Signature <u>Norman D. Hanson</u> Typed or printed name <u>(212) 318-3168</u> Telephone number <u>Oct. 12, 2005</u> Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			

Pre-Appeal Brief Request for Review	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 793658898 US in an envelope addressed to: MS AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.	
Dated: <u>10/12/05</u>	Signature: <u>Jani Malikouzakakis</u> (Jani Malikouzakakis)



LUD 5466.7 DIV (10112540)  
(PATENT)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 7793658998, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 10/12/05

Signature: Fani Malikouzakis  
(Fani Malikouzakis)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Elisabeth Stockert et al.

Application No.: 10/023,182

Confirmation No.: 3379

Filed: December 17, 2001

Art Unit: 1642

For: ISOLATED NUCLEIC ACID MOLECULES  
ENCODING ESO-1 PEPTIDES AND USES  
THEREOF

Examiner: M. T. B. Davis

**PRE-APPEAL REQUEST FOR REVIEW**

MS AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants submit this Pre-Appeal Request for Review because, it is submitted, the Examiner's position with respect to the rejection under 35 U.S.C. § 112, first paragraph, rests on clear errors, which are in turn based upon clear omissions in what is required to sustain the rejection.

The issue in question is the rejection under 35 U.S.C. § 112, first paragraph, wherein the Examiner argues that all claims pending, except claim 41, lack proper written description in the specification. This rejection may be seen in the final rejection of June 3, 2005, specifically at pages 3-4, and the Advisory Action of October 6, 2005, pages 2-7.

The Examiner agrees that the specification adequately describes three species which satisfy the recitation of the broadest claim, i.e., claim 32. These species are presented in claim 41, which has been deemed allowable. The Examiner also agrees that the claims all

require that the amino acid sequences of the claimed proteins be found in SEQ ID NO: 1, which is provided.

The advisory action, however, indicates that the Examiner is reading language into the claims that is not present. For example, at the advisory action, page 3, last two lines, the Examiner states that the claims “read on linear and conformational B cell epitopes.” This, however, is not so. Claim 32 and all dependent claims require processing of T cell epitopes. There is no recitation of B cell epitopes in the claims. In fact, this issue was discussed with the Examiner and the Supervisory Examiner on December 14, 2004. This is reflected, for example, in the amendment of April 1, 2005, at page 4 in particular. As such, any discussions of B cell, or conformational epitopes, are irrelevant as these are different from T cell epitopes. The references the Examiner refers to in the advisory action bear this out. Herbert, et al., The Dictionary of Immunology, page 58 contrasts B cell and T cell epitopes. (Note that the second reference relied upon, i.e., Greenspan, is not prior art).

By reading B cell epitopes into the claims, the Examiner has raised issues that are irrelevant to the question of written description. The issue is simple: does the specification adequately describe proteins which can be processed to T cell epitopes? The Examiner’s answer appears to be “yes, but not enough of them.”

The rationale for this conclusion, however, is flawed. For example, the Examiner argues that no structural relationship is shown.

It is not clear what the Examiner requires by “structural relationship” but the claimed materials must be found in SEQ ID NO: 1. Hence, they do share a structural relationship.

The Examiner claims that the structure of other peptides of the claimed genus were not disclosed. This, too, is incorrect.

As was pointed out, supra, a reference sequence is given. T cell epitopes are limited in their size. They have art recognized lower and upper limits. Applicants made this of record by way of their April 1, 2005 amendment via Marsh, et al., The HLA Facts Book. They also made clear, both via this reference, and the references incorporated by reference at page 25 of the specification, that there are well known rules for MHC-Class I binding. They then followed this with a list of MHC binders, based upon the algorithms that were incorporated by reference.

There is no disagreement on applicants’ part that not every peptide which binds to an MHC Class I molecule will stimulate T cells; however, this is an enablement issue, NOT one of written description, and the Examiner has agreed that the claims are enabled. From the

standpoint of written description, the issue is whether peptides which will function are described. Page 26 lists specific peptides. All of these are found in SEQ ID NO: 1. These proposed MHC Class I binding partners, based upon the incorporated references, are also given. Also described are assays for determining stimulation of T cells (again, an enablement issue, but raised because the Examiner seems to be concerned about this).

It is also submitted that the Examiner has improperly construed the Interim Written Description Guidelines. In their August 3, 2005 response, applicants drew the Examiner's attention to Example 14 of these Guidelines. They describe a claim to proteins which are "at least 95% identical" to a reference sequence, and possess a specific property. Only the full length, non-modified sequence is described, but the claim was deemed to satisfy the Written Description Requirement.

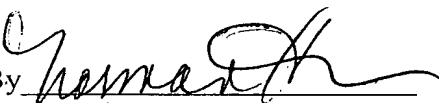
In the present case, no variation from a reference sequence is permitted. Three species within the claimed genus are shown to work. Hence, the Guidelines should be followed, and the claims be held to satisfy the Written Description requirement.

It is requested that review be under taken, and that this application be allowed.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-LUD 5466.7 DIV (10112540) from which the undersigned is authorized to draw.

Respectfully submitted,

By 

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